WASHINGTON D.C. – Rep. Darrell Issa, the Ranking Member of the Oversight and Government Reform Committee, **sent a letter today** to the Inspector General for the Health and Human Services (HHS) Daniel Levinson asking that he "initiate an investigation to determine if FDA employees…have purposely and improperly sought to impede and mislead a Congressional oversight investigation." The Committee is investigating consumer safety failures at Johnson & Johnson, including the recall of Motrin caplets by Johnson & Johnson's subsidiary McNeil Consumer Healthcare (McNeil).

"In the course of this investigation, it has come to my attention that the U.S. Food and Drug Administration (FDA) has (1) issued statements to the media that are inconsistent with key facts related to the investigation; (2) an FDA official apparently attempted to mislead Congress by omitting key facts about FDA's knowledge of Johnson & Johnson's market withdrawal efforts in 2009; and (3) the FDA has refused to make available to Committee investigators an employee with clear first-hand knowledge of an FDA failure," Issa wrote to the IG.

On April 21, 2009, McNeil's Quality Site Leader of the Las Piedras, Puerto Rico plant, Mayra Pujals, filed a Field Action Report (FAR) with the FDA San Juan Office District Director Maridalia Torres notifying the FDA that Motrin had been and would continue to be removed

from store shelves. The report states clearly:

As stated in the previous Field Alert Report follow-up issued on March 23, 2009, in order to confirm the availability of Motrin batches SHC003 and SHC004 at the retail level, a statistical sampling of approximately ten (10) percent of stores across the US that received these batches were visited (250 stores out of 2000)….**The product from the subject lots found in the stores was removed during the visits. Visits to remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.**

In a *Reuters* article dated September 21, 2010, FDA spokeswoman Elaine Bobo denied that, until July 2009, her agency was aware of an effort to remove Motrin from store shelves as part of a market withdrawal that has been popularly dubbed McNeil's "phantom recall" of Motrin. Specifically, Ms. Bobo said:

Any effort to suggest to the contrary [that FDA had knowledge of the "phantom recall"] is based on quoting documents selectively and out of context and ignores other evidence as to what occurred.

McNeil's own written account of its communications with FDA does not support the conclusion that McNeil disclosed the activities associated with its 'phantom recall' to FDA.

Likewise, a September 22, 2010, *CNN* article quotes an unnamed FDA source, who continues to contend on behalf of the agency, that the FDA first learned about the Motrin purchase effort in July 2009. According to an FDA statement cited by
CNN
:

When the FDA learned that McNeil had hired contractors to secretly purchase product off the shelves, the agency advised McNeil to do a full recall which the company agreed to initiate in July 2009. FDA then voiced its objections about McNeil's 'phantom recall' activities to the senior leadership of Johnson & Johnson in a February 2010 meeting.

At the Committee's hearing on May 27, 2010, FDA's witness, Dr. Joshua Sharfstein, omitted communications by McNeil employees to FDA about the Motrin market withdrawal efforts in recounting a sequence of events. His testimony paints a deeply misleading sequence of events that many interpreted to mean that FDA first learned of the Motrin market withdrawal efforts from a state agency in July 2009. Specifically, he said:

The company notified FDA that they were going to be evaluating whether there was product on the shelves to recall. **Then we were alerted, I believe, by one of the State Boards of Pharmacy** that instead of just looking to see whether or not there was medication to recall, the company had a contractor that was going out and trying to buy up….

On Thursday, September 23, 2010, Committee Minority Staff requested that FDA make San Juan District Office Director Maridalia Torres available to speak with Committee staff about events surrounding the Motrin recall and the FDA's knowledge of such efforts. As mentioned earlier, Ms. Torres' name appears again and again in emails from McNeil officials referencing contact with FDA about the Motrin recall. Ms. Torres was also the named recipient of McNeil's April 21, 2010, FAR overtly stating a plan to continue efforts to remove Motrin from store shelves, through a market withdrawal. On Friday, September 24, 2010, FDA officials informed

Committee staff that Ms. Torres would not be made available to speak with investigators.

"While the documented facts appear to make clear that FDA – by April 21, 2010 at the latest – was made aware of the effort to remove Motrin from store shelves by contractors conducting a market withdrawal, FDA officials have publicly stated a very different sequence of events" wrote Issa. "FDA officials appear to have purposely and improperly sought to impede and mislead a Congressional oversight investigation through press statements, Congressional testimony, and the denial of access to a relevant witness. FDA has also so far failed to produce documents requested by Chairman Edolphus Towns that are of critical importance for a hearing scheduled for September 30, 2010. Taken together, there appears to be an egregious and intentional effort by a regulatory entity entrusted with the public health, to mislead the American public and avoid accountability."

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